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(54) **Two-way outdwelling slit valve assembly.**

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Description

Field of Invention

The present invention relates generally to medical liquid flow in a cannula and more particularly to novel structure and methods for outdwelling selective slit valving of medical liquid flow, including bi-direction flow, along a cannula, such as a catheter tube or needle, when the distal end thereof is indwelling in a medical patient.

Such a valve structure is known from US-A-4 904 245 which forms the preamble of claims 1, 15 and 16.

Background and Related Art

It has long been recognized to be medically desirable to intravenously infuse liquid into and to sample blood from a patient. Certain problems have, nevertheless, persisted over the years in the fields of intravenous (IV) infusion and acquisition of blood specimens.

Typically, during delivery of IV solution to the patient through a cannula, such as a catheter tube or IV needle, it is difficult to predict when the supply of IV solution will become exhausted and even more difficult to coordinate availability of nursing personnel with the need to timely disconnect a soon-to-be-dry IV supply from the catheter tube or needle. As a consequence, the distal tip of the cannula sometimes experiences bleedback and clotting. More specifically, in a conventional IV hook-up to a patient, the flow of IV solution occurs because the force of gravity upon the solution exceeds the blood pressure in the cardiovascular system of the patient. When the supply of IV solution is exhausted, the pressure difference changes so that the cardiovascular pressure prevails, causing blood flow into the IV catheter tube a distance which may vary. Sometimes this blood flow reaches, contaminates and requires replacement of the IV filter. In any event, whether the blood reaches the filter or it does not, the aforesaid blood in the catheter will, within a short time, clot. This risks negligent introduction of the clot into the bloodstream and requires replacement of the IV system, when discovered.

Also, shifting of positions by the patient, as, for example, if the patient raises the venipuncture site above the IV bottle, sometimes causes refluxing or bleedback of blood into the distal end of the cannula. This reflux may or may not reach the IV filter, but in either event causes IV flow to stop which results in clotting within either the cannula, the filter or both.

When and if discovered, both the clotted IV filter and catheter tube are replaced with the accompanying patient trauma and expense. It is bad practice and an unacceptable risk to the patient to force a clot from the catheter tube into the bloodstream, but, due to negligence, this sometimes happens.

It has been proposed that a one-way outdwelling (outside the patient) standard valve be used to prevent undesired blood flow into the distal end of an indwelling cannula, such as a catheter tube or IV needle. However, this approach does not work in a medically-acceptable fashion. Also, the one-way standard valve will not allow blood sampling when the standard one way valve is located between the catheter tube and the sampling site.

US-A-4904 245 discloses an arrangement for irrigating a patient's bladder comprising a surgical valve having a molded plastic body comprising five circumferentially spaced ports. A first port comprises a connection to a source of fluid, a second port comprises a connection to a syringe through a split valve, a third port comprises a connection to a waste receptacle, a fourth port comprises a connection to a patient catheter, and a fifth port comprises a connection to a second patient catheter or a second lumen of a multi-lumen catheter.

The fluid flowing into the valve is derived from the fluid source through the first port, requiring manipulation of the valve to direct such fluid from the source to one of the patient catheters, to the syringe, or to the waste receptacle.

Fluid from the source can flow to the patient by one of two paths. When the valve is set in a first position, fluid flows through a direct first path outward through the fifth port. The second path is more circuitous: the valve is set to a second position and fluid is drawn from the source through the split valve and into the syringe by reciprocation in a first direction; the valve is then set to a third position and the syringe is reciprocated in a second direction to force liquid back through split valve and to the patient via the fourth port.

Thus, in the case of the first path, fluid flows directly to the patient without being inhibited by a valve of any kind when the valve is in the first position. Otherwise, fluid from the source cannot flow directly to the patient. It must first course through split valve 18 in one direction under manipulation of the syringe with the valve set in the second position and then, after the valve is switched to the third position, course once more through split valve as a result of hydrostatic pressure of the syringe to be delivered to the patient through the fourth port. Fluid does not pass from the source to the patient just once through the split valve in either case and, in this prior art arrangement when fluid moves across the split valve, liquid is moved through the split valve by pressures generated by reciprocation of the syringe.

OBJECT OF THE INVENTION

The object of the present invention is to provide an outdwelling, normally closed slit valve by which liquid is selectively communicated to and from a desired internal body location of a medical patient.

Accordingly, the present invention provides two-way medical valve structure for disposition external of a body of a medical patient, the valve structure comprising housing means comprising proximal liquid ingress and egress flow port means, distal liquid ingress and egress flow port means and a hollow interior defining a single flow path through which liquid entering the port means selectively flows in a desired direction and bi-directionally displaceable, pressure-responsive slit valve means transversely disposed within the hollow interior of the housing means and comprising peripheral means imperviously secured at the housing means, the slit valve means further comprising normally closed slit means, with memory comprising opposed lips with contiguous opposed edges held sealingly and alignedly together by said memory only when liquid pressure differential across the slit valve means is within a predetermined range, the edges separating to open the slit valve means only when liquid pressure differential is above or below the predetermined range to accommodate proximal and distal flow respectively along the single flow path in a single direction during liquid egress flow and in the opposite direction during liquid ingress flow, characterized in that the slit valve means further comprises means contiguously associated with the slit means and imperviously secured at the housing means for selectively determining said predetermined range and said range determining means comprise central apertures and are contiguously juxtaposed to said slit means adjacent to said central apertures.

In order that the invention may be more readily understood, embodiments thereof will now be described, by way of example, with reference to the accompanying drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective of one presently preferred out-dwelling, two way, normally closed, pressure responsive slit valve flow control, embodying the principles of the present invention, shown in an installed condition;

Figure 2 is an enlarged cross section taken along lines 2-2 of Figure 1;

Figure 3 is an enlarged fragmentary cross section of the slit of the flow control of Figure 1 flexed open in a distal direction due to pressure differential P_1;

Figure 4 is similar to Figure 3 but shows the slit flexed open in a proximal direction due to pressure differential P_2;

Figure 5 is an enlarged exploded perspective of the slit valve flow control of Figure 1; and

Figure 6 is a cross section of a second presently preferred outdwelling, two-way, normally closed, pressure responsive slit valve flow control for a peripheral catheter tube, according to the present invention.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

Reference is now made to the drawings wherein like numerals are used to designate like parts throughout. Specifically, Figures 1 through 5 illustrate one presently preferred two-way, pressure responsive, outdwelling slit valve flow control mechanism or assembly. Figure 6 illustrates a second, presently preferred slit valve flow control mechanism or assembly. Both of the illustrated embodiments implement the principles of the present invention, the slit valve flow control assembly of Figures 1 through 5 being generally designated 10 and the slit valve flow control mechanism of Figure 6 being generally designated 12.

Valve assembly 10 is illustrated in Figure 1 in an "as used" condition, i.e., where the slit valve assembly 10 is interposed between a cannula in the form of a catheter tube, generally designated 14, and an intravenous (IV) tube, generally designated 16. It is to be appreciated that the IV use depicted in Figure 1 is only exemplary and that the present invention contemplates outdwelling slit valve control for selective delivery of liquid to and from a desired internal location within a medical patient.

The catheter tube 14, illustrated in Figure 1, may be of any conventional type and is illustrated as having a distal end portion 18 comprising a distal port 20 placed indwelling in the cardiovascular system of a medical patient, namely in the patient's vein 22, as illustrated in Figure 1. The catheter tube 14 as illustrated in Figures 1 and 2 comprises a proximal end portion 24 illustrated, in Figure 2, as having been force-fit into suitable liquid communication with the slit valve assembly 10, as hereinafter more fully explained.

Likewise, tube 16 may be of any desired type by which liquid is selectively made available to the slit valve assembly 10. IV tube 16 is illustrated as comprising a distal end portion 26 shown as being force-fit into a secured telescopic liquid communicating relationship with the slit valve assembly 10, as hereinafter more fully described. Tube 16 is also illustrated in Figure 1 as comprising a "Y" site 28, where a hollowed side port 30 emanates. Side

port 30 is illustrated as being closed at its proximal end by a conventional elastomeric cap 32, which may be penetrated by a hypodermic needle, for example, and which will reseal upon removal of the needle. Side port 30 and use of a hypodermic syringe is one presently preferred way by which a blood specimen may be removed from or medication introduced into the vein 22 through the catheter 14 and across the slit valve assembly 10 when predetermined pressure differential conditions are brought into play.

Figure 1 further illustrates IV tube 16 as comprising a proximal end 34 which is illustrated as being connected via a rigid fitting 35 (Fig. 2) to an IV bottle 36 shown suspended by a bracket 38 upon a cantilevered arm 40, all of which is conventional. Thus, under predetermined pressure differential conditions at slit valve control 10, IV solution in bottle 36 is selectively and controllably introduced into the vein 22 from catheter tube 14 across slit valve 10, responsive to a predetermined hydrostatic head.

With reference to Figures 2 through 5, slit valve flow control 10 will now be described. The slit valve flow control 10 comprises a housing, generally designated 42, illustrated as comprising two parts 44 and 46. Housing parts 44 and 46 are preferably formed of shape-retaining synthetic resinous material and are constructed so as to be connected, one to the other, as hereinafter more fully explained. Valve housing part 44 comprises a relatively large annular wall 48, shown as being of substantially uniform thickness and comprising an exposed cylindrical surface 50 and a concealed inner surface 52. Wall 48 terminates in a blunt, transversely oriented edge 54. Interposed between edge 54 and surface 52 are internal threads 56, which form an integral part of wall 48, as illustrated.

Valve housing part 44 also comprises a transversely oriented, radially directed wall 58, which is integral with wall 48 at annular corner 60. Wall 58 is illustrated as having a uniform thickness comprising exposed, external surface 62 and internal surface 64. Wall 48 is interrupted by a centrally disposed aperture 66.

Valve housing part 44 also comprises a distally-extending annular boss in the form of wall 68. Wall 68 is illustrated as having been formed as one piece with, and is, therefore, integral with wall 58 at annular corner 70. Wall 58 is illustrated as being of uniform thickness throughout comprising exterior wall surface 72 and interior wall surface 74. Wall 68 terminates in a transversely oriented blunt edge 76. The diameter of surface 72 is selected, in the illustrated configuration, to be sufficiently greater than the inside diameter of the proximal end 24 of the catheter tube 14 so as to accommodate a satisfactory press-fit relationship between the two, as illustrated in Figure 2. For such a satisfactory relationship to exist, sufficient compressive force must exist between the proximal end 24 of the catheter tube 14 and the wall 68 so that inadvertent separation of the two does not occur. Where permanent attachment is desired, a suitable bonding agent or adhesive may be applied between the proximal end 24 of the catheter tube 14 and surface 72 of wall 68. The diameter of interior surface 74 of wall 68 is selected to accommodate the desired amount of liquid flow therethrough.

Valve housing portion 46 is illustrated as comprising an annular wall 80, which comprises a smooth exterior cylindrical surface 82 and a smooth interior surface 84, which is substantially longer in an axial direction than is surface 82. Surface 82 merges at a 90° angle with radially-directed, exterior surface 86. Wall surface 86 is illustrated as having a radial dimension essentially half that of the radial thickness of wall 80. Wall segment 80 integrally merges with reduced thickness wall segment 88. The interior surface of wall segment 88 is the previously described surface 84, which merges at a 90° angle with transversely directed blunt edge 90 of wall segment 88. Wall edge surface 90 in turn merges substantially at 90° with threaded surface 92 of wall segment 88. Threads 92 are sized and arranged so as to threadedly match previously described threads 56, accommodating threaded joining of valve housing parts 44 and 46. A suitable adhesive is ordinarily placed between threads 56 and 92 to permanently join housing ports 44 and 46 after the interior components have been correctly placed therein.

Wall segment 80 is formed as one piece and, therefore, integrally joins radially directed wall 94 at annular corner 96. Wall segment 94 is illustrated as being of uniform thickness and as comprising exterior or exposed surface 98 and interior or concealed surface 100. Radially-directed wall 98 is illustrated as being centrally apertured at 102.

Valve housing part 46 is further illustrated as comprising a proximally-directed boss in the form of annular wall 104, which is formed as one piece with and is, therefore, integral with radially directed wall 94 at corner 106. Wall 104 is illustrated as being of uniform thickness comprising external cylindrical wall 108 and internal cylindrical wall 110 having a diameter equal to that of aperture 102. Wall segment 104 terminates in transversely directed blunt edge 112 and has sufficient length and internal diameter to accommodate press-fit acceptance of the rigid male fitting 35 conventionally placed at the distal end 26 of IV tube 16 so as to preclude inadvertent separation.

Three disc-shaped elements are carried within slit valve flow control housing 42 when the two parts 44 and 46 are threadedly secured as illus-

trated in Figure 2, namely distal flex control disc 120, proximal flex control disc 122, and central slit diaphragm 124.

Flex control disc 120 is preferably rigid and formed of synthetic resinous materials. Disc 120 is illustrated as comprising a peripheral blunt edge 126 of a disc wall illustrated as being of uniform thickness throughout and comprising distal and proximal flat surfaces 128 and 130, respectively. An aperture 132 is centrally disposed through the disc 120. The diameter of aperture 132 is selected to allow flexing of the diaphragm 124 in a distal direction, as illustrated in Figure 3, when subjected to a positive differential of a predetermined amount (P_1). The resultant pressure P_1 is ordinarily primarily caused by the hydrostatic head of the IV solution and is set so that the slit closes while a desired amount of IV solution remains in the tube 16 proximal of the slit. While the diameter of the aperture 132 is illustrated in Figure 2 as being substantially the same as the diameter of the bore 74, such does not necessarily under all circumstances have to be the case. Also, while the surface defining the aperture 132 is illustrated as being axially disposed, such surfaces may be diagonally or otherwise disposed so long as diaphragm flexing is accommodated at a desired, relatively low pressure differential (diagrammatically illustrated as P_1 in Figure 3). As illustrated in Figure 2, in the assembled condition, distal surface 128 of disc 120 is contiguous with housing surface 64, while proximal surface 130 is contiguous with the distal surface 142 of slit diaphragm 124.

Proximal flex control disc 122 is similar, as illustrated, to disc 120, except the central aperture 132' of disc 122 is of substantially smaller diameter than the diameter of aperture 132. Since disc 122 is otherwise illustrated as being the same as disc 120, identical numerals have been used and no further description is needed. It is to be noted, however, that the diameter of edge 126 of both disc 120 and disc 122 is just slightly less than the diameter of housing surface 52, to accommodate ease of assembly.

In the assembled condition, as can be seen clearly from Figures 2-4, distal surface 128 of flex control disc 122 is contiguous with the proximal surface 144 of the slit diaphragm 124, while a small area of the surface 130 of the flex control disc 122, at the periphery thereof, is contiguous with housing edge 90. It should be readily apparent that the discs 120 and 122 compressively support the slit diaphragm 124 in its radial orientation, except to permit the diaphragm 124 to centrally flex distally and proximally, depending upon pressure differential conditions. Because the diameter of aperture 132' of disc 122 is illustrated as being materially less than the diameter of aperture 132, central flexing of the diaphragm 124 more readily occurs in a distal direction than in a proximal direction. Other configurations, however, are within the scope of the present invention.

In the embodiment of Figures 1-5, a relatively high pressure differential (diagrammatically illustrated as P_2 in Figure 4), which flexes the diaphragm 124 proximal into aperture 132' to open slit 146 is required to draw blood proximally through the slit 146 of the diaphragm 124, using, for example, a syringe inserted through elastomeric cap 32 at side port 30 of the IV tube 16. In the embodiment of Figure 3, a lower pressure differential (diagrammatically illustrated as P_1 in Figure 3) caused in part by the weight of the IV solution in tube 16, which flexes diaphragm 124 distally into the larger aperture 132 to open the slit 146, is required for IV solution to flow.

Slit diaphragm 124 is disc-shaped and is formed of a suitable elastomeric material, such as silicone rubber. Silicone rubber offers the advantage of ease in centrally flexing the diaphragm coupled with good memory characteristics. In an unstressed condition, diaphragm 124 is illustrated (in Figure 2) as being planar and of uniform thickness, comprising edge 140, the unstressed diameter of which is slightly less than the diameter of housing wall 52. The diaphragm 124 is illustrated as being of uniform thickness comprising distal, radially-directed flat surface 142 and proximal, radially-directed flat surface 144.

Diaphragm 124 comprises a centrally-disposed, normally closed, transversely-directed linear slit 146. Slit 146 is illustrated as uniformly extending from surface 142 to surface 144 and is located so as to be directly aligned with previously mentioned apertures 132 and 132', when placed in the assembled position of Figure 2. The radial length of slit 146 is selected to accommodate the degree of distal and proximal flexing needed in order to accommodate selective bi-directional liquid flow through the flexed and open slit 146 to introduce, for example, IV solution into the patient under hydrostatic IV pressure or to remove sample blood from the patient under negative pressure or to introduce medication into the bloodstream. In addition to the length of the slit 146, the material used to form the diaphragm 124, the thickness of the diaphragm and the size of apertures 132 and 132' individually and collectively are variables to be set in determining the pressure differentials (diagrammatically illustrated in Figures 3 and 4 as P_1 and P_2) by which the slit 146 is caused to be opened distally and proximally.

It is also to be appreciated that outdwelling fluid control devices according to the present invention can be free standing, for addition to a cannula, such as a catheter or a needle, at the time

of use, or can be constructed as a component part of an IV cannula system at the time of manufacture.

Using the slit valve flow control 10 in conjunction with the rest of the system illustrated in Figure 1, it is to be appreciated that the IV system never runs dry because the flexure in a distal direction required at slit 46 (diagrammatically illustrated as P_1 in Figure 3) ceases to exist while the IV tube 16 is still partially or entirely filled with IV solution. Consequently, it is not possible for bleed-back into and clotting within the catheter tube or other IV cannula to occur. Thus, cannula and/or IV filter replacement due to bleed-back contamination is avoided. When blood sampling occurs via side port 30, the presence of IV solution in the system returns residual blood left in the IV set to the vein 22 immediately following termination of the blood withdrawal cycle. Also, since a blood clot in the cannula, such as catheter tube 14, is not possible, it is correspondingly impossible for a blood clot to be inadvertently discharged from the catheter tube into the vein.

The same essential result may be accomplished using the slit valve flow control mechanism 12, shown in Figure 6, in lieu of the slit valve flow control assembly 10 of Figures 1 through 5. Slit valve flow control mechanism 12 comprises a housing 150 comprising two housing parts, generally designated 152 and 154, respectively.

Housing part 152 comprises a wall 156, illustrated as being of uniform thickness. The wall 156 comprises, as illustrated, an upper surface 158, part of which is exposed and part of which is concealed, and a concealed inside surface 168. Wall 156 also comprises an exposed edge surface 160. A male extension 162 projects downwardly from its integral connection with wall 156. Extension 162 exteriorly comprises surface 160, a blunt edge 164 and internal surface 166. Thus, wall extension 162 in conjunction with wall 156 forms a recess at internal surface 168. Wall 156 and recess at 168 are interrupted by a centrally disposed aperture 170, which extends through wall 156. The diameter of aperture 170 is selected so as to accommodate proximal flexing of an associated diaphragm 220 under a relatively high pressure differential (P_2) for blood sampling, consistent with the preceding description.

Valve part 152 comprises a proximal liquid flow passageway 172. Passageway 172 is defined by a liquid flow port wall, generally designated 174. Port wall 174 comprises a lower wall segment 176, shown as having a uniform thickness, which integrally is an extension of wall 156 and terminates in a blunt annular edge 178. Proximal port wall 174 also comprises a curved wall segment 180, which is also integral in part with wall 156 and terminates in the previously mentioned blunt edge 178. Directly adjacent blunt edge 178 is a curved segment 181 of the port wall 174, accommodating press-fit internal receipt of rigid fitting 35 at the distal end 26 of the IV tube 16, in the manner heretofore mentioned. The passageway 172 is sized to accommodate sufficient IV, medication and/or blood sampling flow to accomplish the objectives of the invention.

As is the case with housing part 152, housing part 154 is formed as one piece, preferably of rigid synthetic resinous material. Valve housing part 154 comprises a wall 190 which comprises an exterior edge 192, which merges at 90° with shoulder 194. Shoulder 194 merges at 90° with a reduced diameter surface 196, sized and shaped to press fit against the surface 166. It is presently preferred that surfaces 166 and 196 be permanently secured to each other as illustrated using a suitable adhesive. Surface 196 merges through 90° with an abutment surface 198, which has a relatively short transverse distance. Abutment surface 198 merges with a downwardly convergent recessed surface 200. Surface 200 defines an aperture or orifice 202 at the base thereof which lies in the same plane as the bottom surface 204 of wall 190.

As can be seen by inspection of Figure 6, wall surface 204 is partly exposed and partly concealed. The concealed portion of surface 204 falls within a liquid flow passageway 206.

Passageway 206 is defined by liquid port wall structure 208, which comprises a thin tube-connecting annular wall extension or lip 210 integral with wall 190, and a curved wall 212, which is also integral with wall 190. Annular wall extension 210 and wall 212 are integral and together terminate in blunt edge 214 at the distal end of the passageway 206. The exterior surface 216 adjacent edge 214 is of such a diameter to accommodate external press-fit connection of the proximal end 24 of the catheter tube 14, in the manner heretofore explained.

From a visual inspection of Figure 6, it is readily apparent that abutment surface 198 is spaced a predetermined distance from surface 168 of wall 156 when the housing parts 152 and 154 are fully assembled. The space between surfaces 198 and 168 is preferably slightly less than the thickness of a rectangular diaphragm 220. Rectangular diaphragm 120 is illustrated as being of uniform thickness, preferably slightly more than the distance between surfaces 198 and 168 so as to be compression held between surfaces 168 and 198 in the illustrated assembled condition. Diaphragm 220 also comprises a central, normally closed, pressure responsive linear slit 222 which, under predetermined pressure differential conditions selective accommodates bidirectional liquid flow therethrough, flexing in the proximal direction being accommo-

dated by relatively high proximally directed pressure differential P_2 and flexing to an open position being accommodated in a distal direction under relatively low distally directed pressure differential P_1, such distal flexing being readily accommodated by conical surface 200 of valve housing 154.

In terms of use, since the slit valve flow control mechanism 12 is operatively substantially the same as the already described slit valve flow control mechanism 10, no further operative description is needed.

The features disclosed in the foregoing description, in the following claims and/or in the accompanying drawings may, both separately and in any combination thereof, be material for realising the invention in diverse forms thereof.

Claims

1. Two-way medical valve structure (10 or 12) for disposition external of a body of a medical patient, the valve structure comprising housing means (42 or 150) comprising proximal liquid ingress and egress flow port means (104 and 174), distal liquid ingress and egress flow port means (68 or 208) and a hollow interior (110, 100, 74 or 172, 170, 206) defining a single flow path through which liquid entering the port means selectively flows in a desired direction and bi-directionally displaceable, pressure-responsive slit valve means (120, 124, 122 or 168, 220, 198) transversely disposed within the hollow interior of the housing means and comprising peripheral means imperviously secured at the housing means, the slit valve means further comprising normally closed slit means (124, 146 or 220, 222) with memory comprising opposed lips with contiguous opposed edges held sealingly and alignedly together by said memory only when liquid pressure differential across the slit valve means is within a predetermined range, the edges separating to open the slit valve means only when liquid pressure differential is above or below the predetermined range to accommodate proximal and distal flow respectively along the single flow path in a single direction during liquid egress flow and in the opposite direction during liquid ingress flow, characterized in that the slit valve means further comprises means (120, 122 or 168, 198) contiguously associated with the slit means and imperviously secured at the housing means for selectively determining said predetermined range and said range determining means (120, 122 or 168, 198) comprise central apertures (132, 132' or 170, 200) and are contiguously juxtaposed to said slit means adjacent to said central apertures.

2. The valve structure according to Claim 1, wherein the slit valve means comprise an elastomeric diaphragm (124 or 220) comprising at least one slit (146 or 222), the diaphragm being flexed to separate the lip edges only when the liquid pressure differential is above and below the range.

3. The valve structure according to Claim 2, wherein the diaphragm (124 or 220) is flat, of a predetermined substantially uniform thickness and comprises a slit (146 or 122) of predetermined length.

4. The valve structure according to Claim 2, wherein the diaphragm (124) comprises an elastomeric disc.

5. The valve structure according to Claim 2, wherein the diaphragm (220) comprises a rectangular shape.

6. The valve structure according to Claim 1, wherein the housing means comprise at least two parts (44, 46 or 174, 208) fastened together.

7. The valve structure according to Claim 6, wherein the two parts comprise complementary threadedly connecting means (56, 92).

8. The valve structure according to Claim 1, wherein the slit valve means comprise first contiguously associated means (120 or 198) distally adjacent to an interposed diaphragm (124 or 220) and second contiguously associated means (122 or 168) proximally adjacent to the diaphragm, which first and second contigously associated adjacent means separately constrain flexure of the diaphragm distally and proximally to control at least in part the respective pressure differentials required to distally and proximally open the slit means.

9. The valve structure according to Claim 8, wherein the first and second contiguously associated diaphragm constraining means (120, 122 or 190, 156) respectively comprise larger and smaller aperture means (132, 132' or 202, 170) adjacent and aligned with the slit (146 or 222), the smaller aperture means (132' or 170) requiring a greater pressure differential to open the slit and the larger aperture means (132 or 202) requiring a lesser pressure differential to open the slit.

10. The valve structure according to Claim 8, wherein the distal and proximal contiguously

associated adjacent means comprise rigid structure aperture-defining means (122, 124, 132, 132' or 168, 200, 202, 170).

11. The valve structure according to Claim 10, wherein the aperture-defining means comprise a relatively large flow opening (132 or 202) in one direction away from the diaphragm means and a relatively small flow opening (132' or 170) in an opposite direction away from the diaphragm means.

12. The valve structure according to Claim 10, wherein the rigid structure-defining means comprise means (64, 90 or 156, 190) integral with the housing means.

13. The valve structure according to Claim 1, wherein the slit valve means comprise diaphragm means (124 or 220) and the housing means (42 or 15) comprise opposed abutment means (120, 122, or 198, 168) for sealingly securing the diaphragm means.

14. The valve structure according to Claim 1, wherein the slit valve means comprise yieldable diaphragm means (124 or 220) in which at least one slit (146 or 222) is centrally disposed and flexed by pressure differential, and physical means (120, 122 or 168, 198) adjacent to the diaphragm means constraining flexure of the diaphragm means to control the pressure differentials required to open the at least one slit in either direction.

15. A cardiovascular assembly comprising a cannula (14) comprising a hollow interior for placement, at a distal end (18) thereof, in a cardiovascular system (22) of a patient; an effluent only source of uncontaminated medical liquid (36) disposed to provide gravity caused fluid flow to the patient; a hollow tube (16) disposed external of the patient, a proximal interior of the hollow tube being in direct liquid and pressure communication with the liquid at the source (36); the cardiovascular assembly characterized by a two-way valve structure (10 or 12) according to any preceding claim interposed between the hollow tube (16) and the cannula (14) externally of the patient, a proximal part (104 or 174) of the two-way valve structure being in communication with the interior of the hollow tube, at a distal end thereof, and a distal part (68 or 208) of the two-way valve structure being in communication with the hollow interior of the cannula, at a proximal end thereof; said-pressure responsive slit valve means selectively accommodating liquid flow in a distal direction directly from the effluent only source to the patient when the gravity caused pressure predominates by a predetermined magnitude.

16. A method of assembling a two way medical valve comprising providing housing means (42 or 150) therefor comprising bi-directional flow path means (48, 68, 80, 104 or 174, 208), the method being characterized by interposing a normally closed slit diaphragm (124 or 220) between two contiguously adjacent diaphragm flexure constraining means (120, 122, 200 or 168) and sealingly and imperviously securing peripheral means of said diaphragm transversely across said flow path means within said housing such that the slit (146 or 222) of said diaphragm opens in a first direction responsive only to a first pressure differential across the diaphragm of at least a first predetermined magnitude imposed thereon and opens in a second, opposite, direction only responsive to a second, oppositely directed, pressure differential of at least a second predetermined magnitude across the diaphragm thereby permitting flow only through an orifice formed by the so opened slit.

17. The method according to claim 16 wherein the interposing step comprises selecting each flexure constraining means such that each flexure constraining means comprises an annular opening (132, 132' or 170, 200) of a predetermined size displaced to provide an opening over at least a part of said slit and thereby determine at least in part either the first or second magnitude of said first or second pressure differentials, respectively.

18. The method according to claim 16 comprising the further step of joining two parts of a two part housing means (44, 46, or 152, 154) to complete the assembly.

19. The method according to claim 18 wherein the joining step comprises threadably affixing the parts to each other.

Patentansprüche

1. Medizinischer Zweiweg-Ventilaufbau (10 oder 12) zur Anordnung außerhalb des Körpers eines Patienten, mit Gehäusemitteln (42 oder 150) mit proximalen Portmitteln (104 und 174) zum Einlaß und zum Auslaß einer Flüssigkeit und einem hohlen Inneren (110, 100, 74 oder 172, 170, 206), das einen einzigen Flußweg bildet, durch den die Flüssigkeit, die die Port-

mittel erreicht, wahlweise in eine gewünschte Richtung fließt, und in zwei Richtungen verlagerbare, auf den Druck ansprechende Spaltventilmittel (120, 124, 122 oder 168, 220, 198), die quer in dem hohlen Inneren der Gehäusemittel angeordnet sind, und mit Umfangsmitteln, die undurchlässig an den Gehäusemitteln angebracht sind, wobei die Spaltventilmittel weiter in Ruhestellung geschlossene Schlitzmittel (124, 146 oder 220, 222) mit einer Rückstelleigenschaft haben, mit gegenüberliegenden Lippen mit aneinander anliegenden, einander gegenüberliegenden Rändern, die nur dann durch die Rückstelleigenschaft dichtend und aneinanderanliegend gehalten werden, wenn die Flüssigkeitsdruckdifferenz über dem Spaltventilmittel innerhalb eines vorgegebenen Bereiches ist, die Ränder sich zum Öffnen der Spaltventilmittel nur dann öffnen, wenn die Flüssigkeitsdruckdifferenz oberhalb oder unterhalb des vorgegebenen Bereichs sind, um einen proximalen bzw. distalen Fluß entlang des einen Flußwegs in eine Richtung während des Flüssigkeitsabflusses und in der entgegengesetzten Richtung während des Flüssigkeitszuflusses zu erlauben, dadurch gekennzeichnet, daß das Ventilmittel weiter Mittel (120, 122 oder 168, 198) aufweisen, die an dem Spaltmittel anliegend diesem zugeordnet sind und dichtend an dem Gehäusemittel angeordnet sind zum wahlweisen Bestimmen des vorgegebenen Bereichs, und daß die den Bereich bestimmenden Mittel (120, 122 oder 168, 198) zentrale Öffnungen (132, 132' oder 170, 200) aufweisen und an den Spaltmitteln anliegend benachbart den zentralen Öffnungen gegenüberliegend angeordnet sind.

2. Der Ventilaufbau nach Anspruch 1, wobei das Spaltventilmittel eine elastomere Membran (124 oder 220) mit wenigstens einem Spalt (146 oder 222) aufweist, und die Membran verbogen wird, um die Ränder der Lippen nur dann voneinander zu lösen, wenn die Flüssigkeitsdruckdifferenz oberhalb und unterhalb des Bereiches ist.

3. Der Ventilaufbau nach Anspruch 2, wobei die Membran (124 oder 220) flach und von einer vorgegebenen, im wesentlichen gleichförmigen Dicke ist und einen Spalt (146 oder 122) von einer vorgegebenen Länge hat.

4. Der Ventilaufbau nach Anspruch 2, wobei die Membran (124) eine elastomere Scheibe aufweist.

5. Der Ventilaufbau nach Anspruch 2, wobei die Membran (220) eine rechteckige Form hat.

6. Der Ventilaufbau nach Anspruch 1, wobei die Gehäusemittel wenigstens zwei Teile (44 46 oder 174, 208) aufweisen, die aneinander befestigt sind.

7. Der Ventilaufbau nach Anspruch 6, wobei die beiden Teile mit komplementären Gewinden versehene Verbindungsmittel (56, 92) aufweisen.

8. Der Ventilaufbau nach Anspruch 1, wobei das Spaltventilmittel erste aneinander anliegend zusammenwirkende Mittel (120 oder 198), die einer dazwischenliegenden Membran (124 oder 220) distal benachbart sind und zweite aneinander anliegend zusammenwirkend Mittel (122 oder 168) aufweisen, die proximal der Membran benachbart sind mit ersten und zweiten aneinander anliegend zugehörigen benachbarten Mitteln, die getrennt die Biegung der Membran distal und proximal begrenzen, um wenigstens teilweise die jeweiligen Druckdifferenzen, die zum distalen und proximalen Öffnen der Spaltmittel erforderlich sind, zu steuern.

9. Der Ventilaufbau nach Anspruch 8, wobei das erste und das zweite anliegend zugehörige, die Membran zurückhaltende Mittel (120, 122 oder 190, 156) jeweils größere oder kleinere Öffnungsmittel (132, 132' oder 202, 170) benachbart und ausgerichtet mit dem Spalt (146 oder 222) hat, wobei die kleineren Öffnungsmittel (132' oder 170) eine größere Druckdifferenz zum Öffnen des Spaltes und die größeren Öffnungsmittel (132 oder 202) eine geringere Druckdifferenz zum Öffnen des Spaltes erfordern.

10. Der Ventilaufbau nach Anspruch 8, wobei die distal und proximal anliegenden zugehörigen benachbarten Mittel die Öffnung definierende Mittel (122, 14, 132, 132' oder 168, 200, 202, 170) mit festem Aufbau sind.

11. Der Ventilaufbau nach Anspruch 10, wobei die die Öffnung definierenden Mittel eine relativ große Strömungsöffnung (132 oder 202) in einer Richtung weg von den Membranmitteln und eine relativ kleine Strömungsöffnung (132' oder 170) in einer entgegengesetzten Richtung weg von den Membranmitteln haben.

12. Der Ventilaufbau nach Anspruch 10, wobei die die feste Struktur definierenden Mittel Mittel

(64, 90 oder 156, 190) aufweisen, die mit den Gehäusemitteln integral sind.

13. Der Ventilaufbau nach Anspruch 1, wobei die Spaltventilmittel Membranmittel (124 oder 220) aufweisen und die Gehäusemittel (42 oder 15) gegenüberliegende Anschlagmittel (120, 122 oder 198, 168) zum dichtenden Sichern der Membranmittel aufweisen.

14. Der Ventilaufbau nach Anspruch 1, wobei die Spaltventilmittel nachgiebige Membranmittel (124 oder 220) aufweisen, in denen wenigstens ein Spalt (146 oder 222) zentral angeordnet ist und durch eine Druckdifferenz gebogen wird und gegenständliche Mittel (120, 122 oder 168, 198) benachbart den Membranmitteln vorhanden sind, um die Biegung der Membranmittel zu behindern zum Steuern der Druckdifferenzen, die erforderlich sind, um wenigstens einen Spalt in eine Richtung zu öffnen.

15. Eine kardiovaskuläre Anordnung, mit einer Kanüle (14), die ein hohles Inneres zum Einbringen mit ihrem distalen Ende (18) in ein kardiovaskuläres System (22) eines Patienten, einer lediglich zufließenden Quelle einer nicht kontaminierten medizinischen Flüssigkeit (36), die angeordnet ist, um einen von der Schwerkraft verursachten Flüssigkeitsstrom zu dem Patienten zu bewirken, einem hohlen Rohr (16), das außerhalb des Patienten angeordnet ist, einem proximalen Inneren des hohlen Rohres, das in direkter Flüssigkeits- und Druckkommunikation mit der Flüssigkeit an der Quelle (36) ist; wobei die kardiovaskuläre Anordnung gekennzeichnet ist durch einen Zweiweg-Ventilaufbau (10 oder 12) nach einem der vorangehenden Ansprüche, angeordnet zwischen dem hohlen Rohr (16) und der Kanüle (14) außerhalb des Patienten, einem proximalen Teil (104 oder 174) des Zweiwege-Ventilaufbaus in Kommunikation mit dem Inneren des hohlen Rohres an einem distalen Ende von diesem, und einem distalen Teil (68 oder 208) des Zweiwege-Ventilaufbaus in Kommunikation mit dem hohlen Inneren der Kanüle an deren proximalen Ende, wobei der Druck zum wahlweisen Öffnen der Spaltventilmittel zum Durchlassen eines Flüssigkeitsstroms in einer direkten Richtung direkt von der lediglich zufließenden Quelle zu dem Patienten, wenn die Schwerkraft, die von dem Druck erzeugt wird, eine vorgegebene Größe übersteigt.

16. Ein Verfahren zum Montieren eines medizinischen Zweiwege-Ventils, unter Schaffen von Gehäusemitteln (42 oder 150) für dieses, mit einem in zwei Richtung wirkenden Strömungswegmittel (48, 68, 80, 104 oder 174, 208), wobei das Verfahren gekennzeichnet ist durch Anordnen einer in Ruhestellung geschlossenen Spaltmembran (124 oder 220) zwischen zwei fluchtend benachbarten, die Biegung der Membran begrenzenden Mittel (120, 122, 200 oder 168) und abdichtend und sperrend sichernden Umfangsmitteln der Membran quer über das Flußwegmittel innerhalb des Gehäuses derart, daß der Spalt (146 oder 222) der Membran in eine erste Richtung ansprechend nur auf eine erste Druckdifferenz über der Membran von wenigstens einer ersten vorgegebenen Größe, die auf dieses ausgeübt wird, öffnet, und in eine zweite, entgegengesetzte Richtung nur ansprechend auf eine zweite, entgegengesetzt gerichtete Druckdifferenz von wenigstens einer zweiten vorgegebenen Größe über der Membran öffnet, um so einen Fluß nur durch eine Öffnung zu erlauben, die durch den so geöffneten Spalt gebildet wird.

17. Das Verfahren nach Anspruch 16, wobei der Schritt des Anordnens das Auswählen jedes der die Biegung einschränkenden Mittel derart ist, daß jedes die Biegung einschränkenden Mittel eine geringförmige Öffnung (132, 132' oder 170, 200) mit einer vorgegebenen Größe verlagert aufweist, um eine Öffnung über wenigstens einen Teil des Spaltes zu schaffen und dadurch wenigstens einen Teil entweder des ersten oder des zweiten Werts der ersten bzw. der zweiten Druckdifferenz zu bestimmen.

18. Das Verfahren nach Anspruch 16 mit dem weiteren Schritt des Verbindens der beiden Teile eines zweiteiligen Gehäusemittels (44, 46 oder 152, 154) um die Montage abzuschließen.

19. Das Verfahren nach Anspruch 18, wobei der Schritt des Verbindens das schraubbare Befestigen der Teile miteinander beinhaltet.

Revendications

1. Structure de clapet médical bidirectionnel (10 ou 12) à placer à l'extérieur d'un corps d'un patient médical, la structure de clapet comprenant des moyens de boîtier (42 ou 150) comprenant des moyens de port proximal d'écoulement d'entrée et de sortie de liquide (104 et 174), des moyens de port distal d'écoulement d'entrée et de sortie de liquide (68 ou 208) et un intérieur creux (110, 100, 74 ou 172, 170, 206) définissant une unique voix d'écoulement à travers laquelle le liquide entrant dans les moyens de port s'écoule sélectivement suivant

une direction désirée, et des moyens de clapet à fente sensible à la pression, déplaçable bidirectionnellement (120, 124, 122 ou 168, 220, 198), disposés transversalement dans l'intérieur creux des moyens de boîtier et comprenant des moyens périphériques fixés de manière impénétrable aux moyens de boîtier, les moyens de clapet à fente comprenant en outre des moyens à fente normalement fermés (124, 146 ou 220, 222) avec mémoire comprenant des lèvres opposées avec des bords opposés contigus maintenus d'une manière jointive et alignée ensemble par ladite mémoire seulement lorsque le différentiel de pression de liquide sur les moyens de clapet à fente est compris dans un intervalle prédéterminé, les bords se séparant pour ouvrir les moyens de clapet à valve seulement lorsque le différentiel de pression de liquide est supérieur ou inférieur à l'intervalle prédéterminé pour recevoir l'écoulement proximal et distal respectivement le long de l'unique voie d'écoulement suivant une unique direction pendant l'écoulement de sortie de liquide et suivant la direction opposée pendant l'écoulement d'entrée de liquide, caractérisée en ce que les moyens de clapet à fente comprend en outre des moyens (120, 122 ou 168, 198) associé de manière contiguë aux moyens à fente et fixés de manière impénétrable aux moyens de boîtier pour déterminer sélectivement ledit intervalle prédéterminé et lesdits moyens pour déterminer l'intervalle (120, 122 ou 168, 198) comprennent des orifices centraux (132, 132' ou 170, 200) et sont juxtaposés de manière contiguë auxdits moyens à fente adjacents auxdits orifices centraux.

2. La structure de clapet conforme à la revendication 1, dans laquelle les moyens de clapet à fente comprennent un diaphragme en élastomère (124 ou 220) comprenant au moins une fente (146 ou 222), le diaphragme étant fléchi pour séparer les bords de lèvres seulement lorsque le différentiel de pression de liquide est supérieur et inférieur à l'intervalle.

3. La structure de clapet conforme à la revendication 2, dans laquelle le diaphragme (124 ou 220) est plat, d'une épaisseur prédéterminée sensiblement uniforme et comprend une fente (146 ou 122) de longueur prédéterminée.

4. La structure de clapet conforme à la revendication 2, dans laquelle le diaphragme (124) comprend un disque en élastomère.

5. La structure de clapet conforme à la revendication 2, dans laquelle le diaphragme (220) présente une forme rectangulaire.

6. La structure de clapet conforme à la revendication 1, dans laquelle les moyens de boîtier comprennent au moins deux pièces (44, 46 ou 174, 208) fixées ensemble.

7. La structure de clapet conforme à la revendication 6, dans laquelle les deux pièces comprennent des moyens de liaison à vissage complémentaires (56, 92).

8. La structure de clapet conforme à la revendication 1, dans laquelle les moyens de clapet à fente comprennent des premiers moyens associés de manière contiguë (120 ou 198) adjacents de manière distale à un diaphragme interposé (124 ou 220) et des seconds moyens associés de manière contiguë (122 ou 168) adjacents de manière proximale au diaphragme, lesquels premiers et seconds moyens adjacents associés de manière contiguë contraignent séparément le fléchissement du diaphragme de manière distale et de manière proximale pour commander au moins en partie les différentiels de pression respectifs requis pour ouvrir de manière distale et de manière proximale les moyens à fente.

9. La structure de clapet conforme à la revendication 8, dans laquelle les premiers et seconds moyens contraignant le diaphragme associés de manière contiguë (120, 122 ou 190, 156) comprennent respectivement des moyens d'orifices large et étroit (132, 132' ou 202, 170), le moyen d'orifice étroit (132' ou 170) requiérant un différentiel de pression plus grand pour ouvrir la fente et le moyen d'orifice large (132 ou 202) requiérant un différentiel de pression plus petit pour ouvrir la fente.

10. La structure de clapet conforme à la revendication 8, dans laquelle les moyens distaux et proximaux adjacents associés de manière contiguë comprennent des moyens définissant un orifice à structure rigide (122, 124, 132, 132' ou 168, 200, 202, 170).

11. La structure de clapet conforme à la revendication 10, dans laquelle les moyens définissant un orifice comprennent un orifice d'écoulement relativement large (132 ou 202) suivant une direction depuis les moyens de diaphragme et un orifice d'écoulement relativement étroit (132' ou 170) suivant une direction opposée depuis les moyens de diaphragme.

12. La structure de clapet conforme à la revendication 10, dans laquelle les moyens définissant la structure rigide comprennent des moyens (64, 90 ou 156, 190) monolithiques avec les moyens de boîtier.

13. La structure de clapet conforme à la revendication 1, dans laquelle les moyens de clapet à fente comprennent des moyens de diaphragme (124 ou 220) et les moyens de boîtier (42 ou 15) comprennent des moyens de butée opposée (120, 122, ou 198, 168) pour fixer de manière jointive les moyens du diaphragme.

14. La structure de clapet conforme à la revendication 1, dans laquelle les moyens de clapet à fente comprennent des moyens de diaphragme souples (124 ou 220) dans lesquels au moins une fente (146 ou 222) est disposée centralement et fléchie par différentiel de pression, et des moyens physiques (120, 122 ou 168, 198) adjacents aux moyens de diaphragme contraignant au fléchissement des moyens de diaphragme pour commander les différentiels de pression requis pour ouvrir ladite au moins une fente suivant l'une ou l'autre direction.

15. Un assemblage cardio-vasculaire comprenant une canule (14) comprenant un intérieur creux pour placement, à une extrémité distale (18) de celle-ci, dans un système cardio-vasculaire (22) d'un patient ; une source seulement effluente de liquide médical non contaminé (36) disposée pour fournir un écoulement de fluide par gravité au patient ; un tube creux (16) disposé à l'extérieur du patient, un intérieur proximal du tube creux étant en communication directe de liquide et de pression avec le liquide de la source (36) ; l'assemblage cardio-vasculaire étant caractérisé par une structure de clapet bidirectionnelle (10 ou 12) selon une quelconque revendication précédente interposée entre le tube creux (16) et la canule (14) à l'extérieur du patient, une pièce proximale (104 ou 174) de la structure de clapet bidirectionnelle étant en communication avec l'intérieur du tube creux, à une extrémité distale de celui-ci, et une pièce distale (68 ou 208) de la structure à clapet bidirectionnelle étant en communication avec l'intérieur creux de la canule, à une extrémité proximale de celle-ci ; lesdits moyens de clapet à fente sensibles à la pression recevant sélectivement un écoulement de liquide suivant une direction distale directement de la source seulement effluente vers le patient lorsque la pression par gravité prédomine une grandeur prédéterminée.

16. Un procédé d'assemblage d'un clapet médical bidirectionnel comprenant fournir des moyens de boîtier (42 ou 150) comprenant pour celui-ci des moyens de voie d'écoulement bidirectionnelle (48, 68, 80, 104 ou 174, 208), le procédé étant caractérisé par interposer un diaphragme à fente normalement fermé (124 ou 220) entre deux moyens adjacents de manière contiguë contraignant au fléchissement le diaphragme (120, 122, 200 ou 168) et des moyens périphériques de fixation de manière jointive et de manière impénétrable dudit diaphragme transversalement auxdits moyens de voie d'écoulement dans ledit moyen de boîtier de sorte que la fente (146 ou 222) dudit diaphragme s'ouvre suivant une première direction en réponse seulement à un premier différentiel de pression sur le diaphragme d'au moins une première grandeur prédéterminée imposée sur celui-ci, et s'ouvre suivant une seconde direction opposée en réponse seulement à un second différentiel de pression, dirigé de manière opposée, d'au moins une seconde grandeur prédéterminée sur le diaphragme de manière à permettre l'écoulement seulement à travers un orifice formé par la fente ainsi ouverte.

17. Le procédé conforme à la revendication 16 dans lequel l'étape d'interposer comprend sélectionner chaque moyen contraignant au fléchissement de sorte que chaque moyen contraignant au fléchissement comprend un orifice annulaire (132, 132' ou 170, 200) d'une taille prédéterminée décalé pour fournir un orifice sur au moins une partie de ladite fente et de manière à déterminer au moins en partie soit la première soit la seconde grandeur dudit premier ou second différentiel de pression, respectivement.

18. Le procédé conforme à la revendication 16 comprenant en outre l'étape de joindre deux pièces d'un moyen de boîtier à deux pièces (44, 46, ou 152, 154) pour achever l'assemblage.

19. Le procédé conforme à la revendication 18 selon lequel l'étape de joindre comprend fixer par vissage les pièces l'une à l'autre.

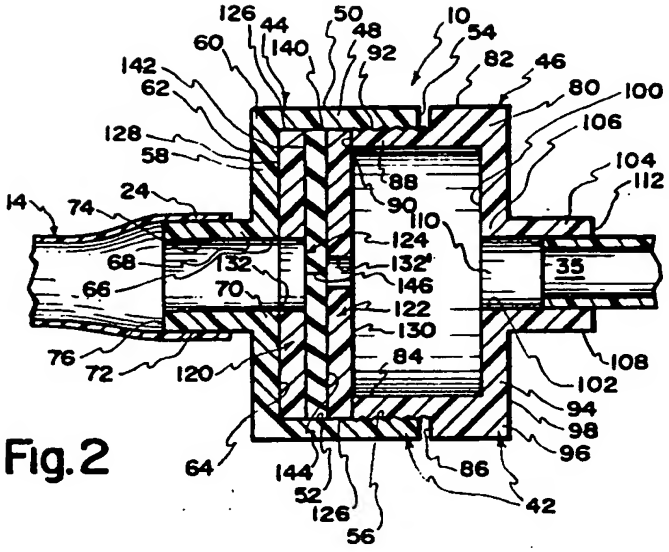


Fig. 2

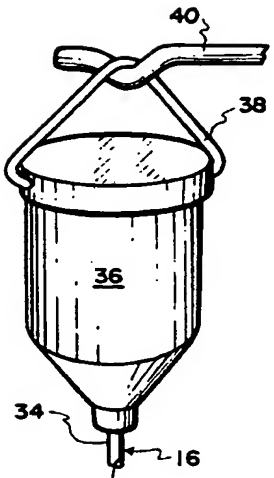
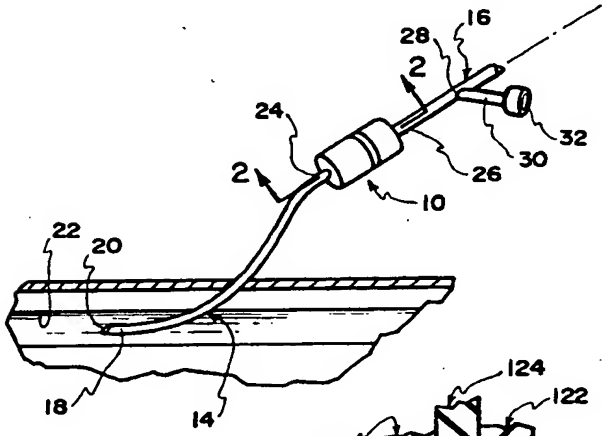


Fig. 1



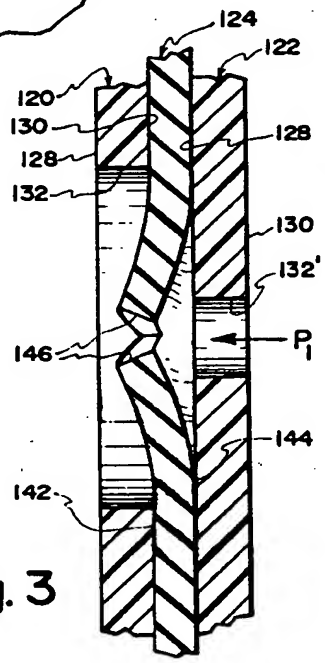


Fig. 3

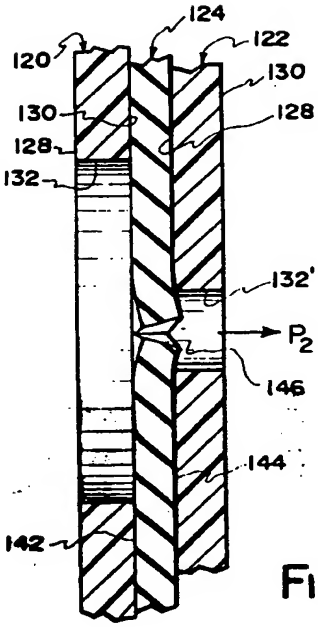
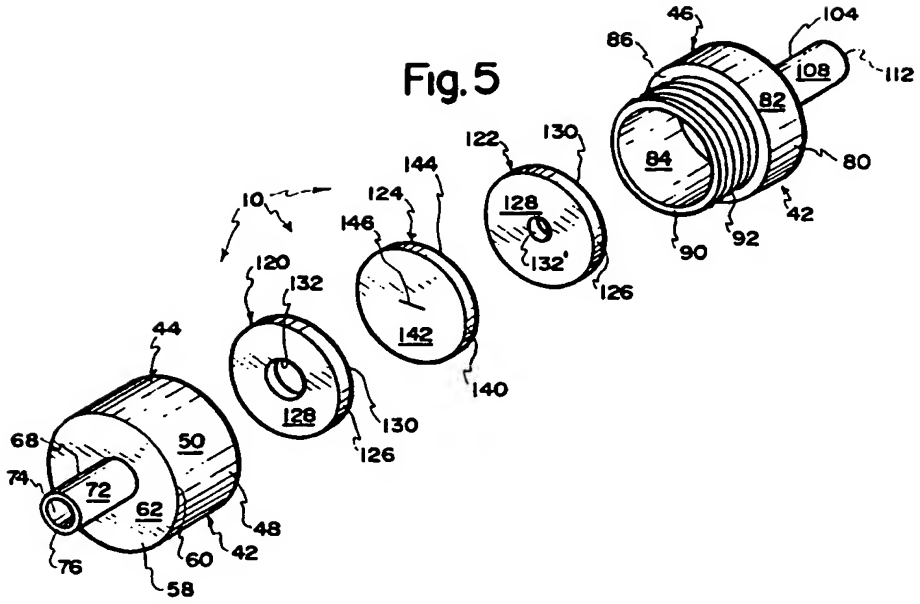


Fig. 4

Fig. 5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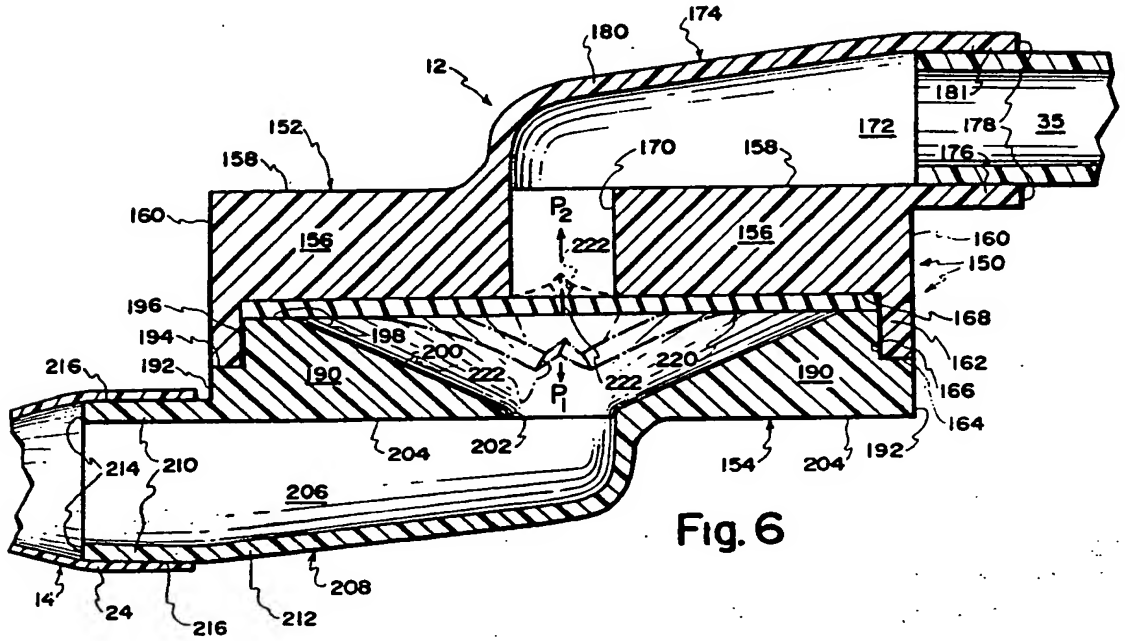
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Fig. 6